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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,909	11/24/2003	Roland Janzen	DCS-9151	5291

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EXAMINER

VENCI, DAVID J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/720,909	Applicant(s) JANZEN ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 12, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 and 14-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action is withdrawn pursuant to 37 CFR 1.114. Applicants' submissions filed on March 27, 2006, and June 12, 2006 are entered.

Currently, claims 1-8, 12 and 14-16 are under examination.

Claims 9-11 and 17-21 remain withdrawn from consideration for being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure is objected to for various informalities. Appropriate correction is required.

In Tables 1-6, the recitation of "Level" is indefinite because it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels"

In paragraph [0035], first sentence, the phrase "the stability study" lacks antecedent basis.

In paragraph [0035], first sentence, the words represented by the abbreviation "TSH" lack antecedent basis.

In paragraph [0035], second sentence, the phrase "the original quantitation" lacks antecedent basis. The identity of one or more objects subject to "quantitation" is not clear.

In paragraph [0036], first sentence, the phrase "but modified beads do not" appears grammatically awkward or misplaced. The identity of objects and/or properties of modified beads that "do not" is not clear and appears omitted.

In paragraph [0037], the pronoun "its" is indefinite. The identity of objects referenced by "its" is not clear.

In paragraph [0037], the phrase "the dissociated molecule" lacks antecedent basis. Whether "the dissociated molecule" references "dissociated species" is not clear.

In paragraph [0038], first sentence, the phrases "the binding pair members" and "the solid-phase" lack antecedent bases.

In paragraph [0040], second sentence, the words represented by the abbreviation "FT3" lack antecedent basis.

In paragraph [0041], second sentence, the adjective "[t]his" is indefinite. The identity of one or more nouns referenced by "[t]his" is not clear.

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Examiner objects to the general contents of paragraphs [0035], [0040], [0041], [0043] and Tables 1-6 for reference to, and reliance upon data obtain from commercially manufactured LOCI™ TSH and FT3 assays. Applicants' specification does not clearly disclose the contents of each of said commercially manufactured assays. Applicants' specification does not clearly disclose experimental protocols for using each of said commercially manufactured assays.

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Claim Rejections - 35 USC § 112

Claims 1-8, 12 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

The objects "an assay" and "an assay of an analyte" are indefinite. The identity of one or more components belonging to "assay" is not clear.

The phrase "attached thereto" is indefinite. The location of "thereto" is not clear. The identity of the entities subject to "attached" is not clear. Whether "first binding species" is attached to "first substrate" AND/OR/NOT "fluid medium" AND/OR/NOT "reagent" is not clear.

Claim 1 appears incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, the structural connection between "fluid medium" and "second substrate" is not clear and appears omitted. The structural connection between "fluid medium" and "binding regions" is not clear and appears omitted. The structural connection between "fluid medium" and "binding partners" is not clear and appears omitted.

The phrase "dissociated first binding species" is indefinite. The identity of two or more objects subject to dissociation is not clear. Whether said "first binding species" is dissociated from "first substrate" AND/OR/NOT "fluid medium" AND/OR/NOT "a second substrate" AND/OR/NOT "binding regions" AND/OR/NOT "binding partners" is not clear.

The phrase "the signal strength" lacks antecedent basis.

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The phrase "detrimentally affecting" lacks antecedent causal basis. The cause(s) of said detrimental effect is not clear.

In claim 7:

In step (2), the relational operator "including" is indefinite in view of "non-porous material" and "outer surface porous". Whether/how a non-porous material can "include" a porous outer surface is not clear.

In step (2), the relational operator "including" is indefinite in view of "non-porous material" and "inner surface". Whether/how a non-porous material can "include" an inner surface is not clear.

Claim 7 appears incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, the structural connection between "fluid medium" and "non-porous material" is not clear and appears omitted. The structural connection between "fluid medium" and "outer surface" is not clear and appears omitted. The structural connection between "fluid medium" and "inner surface" is not clear and appears omitted.

In claim 12:

The phrase "regions adapted to selectively bind" is indefinite. The mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that is/are adapted/modified is not clear.

Claim 12 appears incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, the structural connection between "fluid medium" and "first portion

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of the first binding species" is not clear and appears omitted. The structural connection between "fluid medium" and "second portion of the first binding medium" is not clear and appears omitted. The structural connection between "fluid medium" and "second substrate" is not clear and appears omitted.

In claim 14:

The phrase "attached thereto" is indefinite. The location of "thereto" is not clear. The identity of the entities subject to "attached" is not clear. Whether "first binding species" is attached to "first substrate" AND/OR/NOT "fluid medium" AND/OR/NOT "reagent" is not clear.

The phrase "said dissociated first binding species" lacks antecedent basis.

The phrase "the signal strength" lacks antecedent basis.

The phrase "said assay" lacks antecedent basis. The identity of one or more objects belonging to "assay" is not clear.

The phrase "regions capable of selectively binding" is indefinite. The mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that provide capability is/are not clear.

The duplicate recitation of the term "regions" is indefinite. Whether the space occupied by the first recitation of the term "region" is coextensive with the space occupied by the second recitation of the term "region" is not clear. The degree of coextensive spatial overlap, if any, is not clear.¹

¹ Applicants may obviate this rejection by reciting ordinal descriptors to describe "regions" (e.g., first region, second region).

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The phrase "detrimentally affecting" lacks antecedent causal basis. The cause(s) of said detrimental effect is not clear.

Claim 14 appears incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, the structural connection between "fluid medium" and "second substrate" is not clear and appears omitted. The structural connection between "fluid medium" and each recitation of the term "region" is not clear and appears omitted.

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Claim Rejections - 35 USC § 102

Claims 1-8, 12 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman *et al.* (US 6,406,913).

Ullman *et al.* teach a reagent comprising:

(1) a fluid medium (see col. 36, lines 1-32) containing a first substrate (see col. 19, lines 47-65) having a first binding species (see col. 14, lines 55-67) attached thereto (see col. 19, lines 66-67), said first binding species capable of dissociating from the first substrate (see col. 20, line 8, "non-covalent interactions"); and

(2) a second substrate having binding regions having binding partners capable of selectively binding said first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35).

The language "without detrimentally affecting the signal strength of said assay" does not structurally differentiate Applicants' invention from the reagent of Ullman *et al.* because Examiner considers such language as functional in nature. According to MPEP 2114, a claim containing a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim.

With respect to claims 2-3 and 15-16, Ullman *et al.* teach a reagent wherein the first substrate and second substrates are the same material or different material (see col. 21, lines 23-35).

With respect to claim 7, Ullman *et al.* teach a reagent comprising a non-porous material (see col. 19, lines 47-48) including an outer surface porous to binding species (see col. 21, lines 23-25, "dissolve in"; col.

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22, lines 8-9, "incorporated into") and an inner surface having an affinity for said binding species (see col. 15, lines 38-40).

With respect to claim 12, Ullman *et al.* teach a reagent used in a sandwich type assay (see col. 35, lines 25-33) comprising a first binding species (see col. 37, lines 58+, "TSH"), wherein a first portion (see col. 38, lines 7-9) is attached to the first substrate (see col. 28, line 8, "antibody") and a second portion is dissociated from the first substrate, and the second portion binds to a second substrate (see col. 28, line 8, "the other [antibody]") (paraphrasing mine).

With respect to claim 14, Ullman *et al.* teach a reagent wherein specific binding pair members are located on the surface (see col. 14, lines 55-56) of different supports (see col. 19, lines 47-65) and are used in a competitive assay format (see col. 35, lines 36-38, see col. 37, lines 28-35) wherein one binding member is complementary to the other binding member (see col. 37, lines 28-35).

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Response to Arguments

Specification

In prior Office Action, Examiner objected to the disclosure because, in Tables 1-6, the recitation of "Level" was considered indefinite. Specifically, the identity of the "Level" being measured, or the exact quantity or unit of measurement of the various "Levels" was not clear.

In response, Applicants disclose that "Level" refers to a "calibrator", and a "calibrator" is a standard having a set amount of analyte to be assayed. Applicants further posit that knowledge of calibrator/level units is irrelevant (see Applicants' reply, filed March 27, 2006, p. 3, first paragraph).

Applicants' argument has been carefully considered but is not persuasive.

Examiner is unable to locate a definition for the term "calibrator" in Applicants' specification. In addition, Applicants' specification does not clearly disclose the contents of the commercially manufactured assays using "calibrators" and "level". In addition, Applicants' specification does not clearly disclose experimental protocols for using "calibrators" and "level" in the commercially manufactured assays. Finally, neither Applicants' specification, nor Applicants' Reply disclose the identity of the "Level" being measured, or the exact quantity or unit of measurement of the various "Levels".

Claim Rejections - 35 USC § 112

In prior Office Action, claims 12 and 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the phrases "regions adapted to selectively bind" (claim 12) and "regions capable of selectively binding" (claim 14) were considered unclear. Specifically, the mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that is/are adapted/modified/capable of binding is not clear.

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In response, Applicants point to paragraph [0021] and newly added paragraph [0049] for a description of the term "region", along with paragraphs [0023] and [0032] for a description of a mechanism of pore diffusion (see Applicants' reply, filed March 27, 2006, p. 3, second paragraph).

Applicants' argument has been carefully considered but is not persuasive.

Examiner observes that paragraph [0021] and newly added paragraph [0049] recite language almost identical to the offending language found in rejected claims 12 and 14. With respect to paragraph [0023], Examiner discerns a "scavenger substrate" capturing a "free species", which does not semantically correspond to a "region" binding a "binding species". With respect to paragraph [0032], Examiner discerns a "biotin" binding "streptavidin", which does not semantically correspond to a "region" binding a "binding species".

Claim Rejections - 35 USC § 102

In prior Office Action, claims 1-8, 12 and 14-16 were rejected under 35 U.S.C. 102(b) as being anticipated by Ullman *et al.* (US 6,406,913).

In response, Applicants appear to argue that Ullman *et al.* do not teach:

1. "dissociated" binding species (see Applicants' reply, filed March 27, 2006, paragraph bridging pp. 3-4; see *also* Applicants' reply, filed June 12, 2006, p. 2, fourth paragraph).
2. binding partner that bind "dissociated" binding species (see Applicants' reply, filed March 27, 2006, paragraph bridging pp. 3-4; see *also* Applicants' reply, filed June 12, 2006, p. 2, fourth paragraph).
3. a non-porous material having a porous outer surface (see Applicants' reply, filed March 27, 2006, p. 4, item 2; see *also* Applicants' reply, filed June 12, 2006, paragraph bridging pp. 2-3).

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4. a first portion of a binding species attached to a substrate and a second portion dissociated from the substrate (see Applicants' reply, filed March 27, 2006, paragraph bridging pp. 4-5, *especially* the last sentence; see *also* Applicants' reply, filed June 12, 2006, p. 3, item 3).

Applicants' argument has been carefully considered but is not persuasive.

With respect to 1, Ullman *et al.* describe binding species that are capable of dissociating from a substrate (see col. 20, line 8, "non-covalent interactions").

With respect to 2, Ullman *et al.* describe a second binding partner that binds a first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35).²

With respect to 3, Ullman *et al.* describe a non-porous material (see col. 19, lines 47-48) having a outer surface porous to binding species (see col. 21, lines 23-25, "dissolve in"; col. 22, lines 8-9, "incorporated into").

With respect to 4, Ullman *et al.* describe a binding species (see col. 37, lines 58+, "TSH"), wherein a first portion (see col. 38, lines 7-9) is attached to the first substrate (see col. 28, line 8, "antibody") and a second portion is dissociated from (*i.e.*, separated subunits) the first substrate, and the second portion binds to a second substrate (see col. 28, line 8, "the other [antibody]") (paraphrasing mine).

² With respect to claims 1 and 14, the recited claim language of binding "without detrimentally affecting the signal strength of said assay" is not afforded patentable weight because the claim language is interpreted as a statement that merely states an intended use or intended result of the claimed product invention. According to MPEP 2114, a claim containing a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim.

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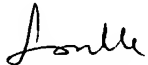
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE 02/19/06
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